



Australian Government

Department of Health and Ageing

**SCHEDULE OF PHARMACEUTICAL
BENEFITS**

SUMMARY OF CHANGES

EFFECTIVE 1 August 2011

PHARMACEUTICAL BENEFITS

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 August 2011. The Schedule is updated on the first day of each month and is available on the Internet at www.pbs.gov.au.

Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 August 2011 and are included, where applicable, in prices published in the Schedule —

Dispensing Fees:	Ready-prepared	\$6.42
	Dangerous drug fee	\$2.71
	Extemporaneously-prepared	\$8.46
	Allowable additional patient charge*	\$3.92
Additional Fees (for safety net prices):	Ready-prepared	\$1.09
	Extemporaneously-prepared	\$1.44
Patient Co-payments:	General	\$34.20
	Concessional	\$5.60
Safety Net Thresholds:	General	\$1317.20
	Concessional	\$336.00
Safety Net Card Issue Fee:		\$8.58

*The allowable additional patient charge is a discretionary charge to general patients if a pharmaceutical item has a dispensed price for maximum quantity less than the general patient co-payment. The pharmacist may charge general patients the allowable additional fee but the fee cannot take the cost of the prescription above the general patient co-payment for the medicine. This fee does not count towards the Safety Net threshold.

SUMMARY OF CHANGES

Additions

Additions – Items

- 8975J **Desmopressin Acetate**, Wafer 240 micrograms (base) (*Minirin Melt*)
- 5270J **Docetaxel**, Solution concentrate for I.V. infusion 20 mg in 1 mL (*Taxotere, Oncotaxel 20*)
- 5272L **Docetaxel**, Solution concentrate for I.V. infusion 80 mg in 4 mL (*Taxotere, Oncotaxel 80*)
- 5271K **Docetaxel**, Injection set containing 1 single use vial concentrate for I.V. infusion 20 mg (anhydrous) in 0.5 mL with solvent (*Taxotere*)
- 5273M **Docetaxel**, Injection set containing 1 single use vial concentrate for I.V. infusion 80 mg (anhydrous) in 2 mL with solvent (*Taxotere*)
- 5490Y **Dutasteride with Tamsulosin**, Capsule containing dutasteride 500 micrograms with tamsulosin hydrochloride 400 micrograms (*Duodart 500ug/400ug*)
- 5277R **Fentanyl**, Transdermal patch 2.55 mg (releasing approximately 25 micrograms per hour) (*Denpax*)
- 5278T **Fentanyl**, Transdermal patch 5.10 mg (releasing approximately 50 micrograms per hour) (*Denpax*)
- 5279W **Fentanyl**, Transdermal patch 7.65 mg (releasing approximately 75 micrograms per hour) (*Denpax*)
- 5280X **Fentanyl**, Transdermal patch 10.20 mg (releasing approximately 100 micrograms per hour) (*Denpax*)
- 5449T **Leflunomide**, Tablet 10 mg (*Arava, Arabloc*)
- 5450W **Leflunomide**, Tablet 20 mg (*Arava, Arabloc*)
- 5263B **Methylprednisolone**, Powder for injection 40 mg (as sodium succinate) (*Methylpred*)
- 5264C **Methylprednisolone**, Powder for injection 1 g (as sodium succinate) (*Methylpred*)

Additions – Brands

- 3058Y *Pharmacor Cephalexin 250, CR* – **Cephalexin**, Capsule 250 mg
- 3317N *Pharmacor Cephalexin 250, CR* – **Cephalexin**, Capsule 250 mg (**Dental**)
- 3119E *Pharmacor Cephalexin 500, CR* – **Cephalexin**, Capsule 500 mg
- 3318P *Pharmacor Cephalexin 500, CR* – **Cephalexin**, Capsule 500 mg (**Dental**)
- 8506Q *Exaccord, RA* – **Exemestane**, Tablet 25 mg
- 8374R *APO-Leflunomide, TX* – **Leflunomide**, Tablet 10 mg
- 8374R *Lunava 10, ZP* – **Leflunomide**, Tablet 10 mg
- 8375T *APO-Leflunomide, TX* – **Leflunomide**, Tablet 20 mg
- 8375T *Lunava 20, ZP* – **Leflunomide**, Tablet 20 mg
- 3495Y *APO-Salbutamol Inhaler, TX* – **Salbutamol Sulfate**, Oral pressurised inhalation 100 micrograms (base) per dose (200 doses), CFC-free formulation (**Emergency Drug Supply**)
- 8288F *APO-Salbutamol Inhaler, TX* – **Salbutamol Sulfate**, Oral pressurised inhalation 100 micrograms (base) per dose (200 doses), CFC-free formulation

Additions – Equivalence Indicators

- 8506Q *Aromasin, PF* – **Exemestane**, Tablet 25 mg
- 8891Y *Durogesic 25, JC* – **Fentanyl**, Transdermal patch 4.2 mg (releasing approximately 25 micrograms per hour)
- 8892B *Durogesic 50, JC* – **Fentanyl**, Transdermal patch 8.4 mg (releasing approximately 50 micrograms per hour)
- 8893C *Durogesic 75, JC* – **Fentanyl**, Transdermal patch 12.6 mg (releasing approximately 75 micrograms per hour)
- 8894D *Durogesic 100, JC* – **Fentanyl**, Transdermal patch 16.8 mg (releasing approximately 100 micrograms per hour)
- 2981X *Solu-Medrol, PF* – **Methylprednisolone**, Powder for injection 40 mg (as sodium succinate) with diluent
- 8834Y *Solu-Medrol, PF* – **Methylprednisolone**, Powder for injection 1 g (as sodium succinate) with diluent

Additions – Notes

- 2981X **Methylprednisolone**, Powder for injection 40 mg (as sodium succinate) with diluent (*Solu-Medrol*)
 8834Y **Methylprednisolone**, Powder for injection 1 g (as sodium succinate) with diluent (*Solu-Medrol*)

Deletions

Deletions – Items

- 8191D **Dolasetron Mesylate**, Tablet 200 mg (*Anzemet*)
 2352T **Glucose Indicator—urine**, Test strips, 50 (*Clinistix*)
 9252Y **Glucose Indicator—urine**, Test strips, 50 (*Clinistix*)

Deletions – Brands

- 2344J *Rithmik 100, QA* – **Amiodarone**, Tablet containing amiodarone hydrochloride 100 mg
 1472L *Fluconazole Winthrop, WA* – **Fluconazole**, Capsule 100 mg
 8561N *Meloxicam Winthrop, WA* – **Meloxicam**, Tablet 7.5 mg
 8562P *Meloxicam Winthrop, WA* – **Meloxicam**, Tablet 15 mg
 2285G *Zabel, AF* – **Terbinafine**, Tablet 250 mg (as hydrochloride)
 2804N *Zabel, AF* – **Terbinafine**, Tablet 250 mg (as hydrochloride)

Alterations

Alterations – Item Description

From:

5407N **Fentanyl**, Lozenges 200 micrograms (as citrate), 3 (*Actiq*)(**Palliative Care**)

To:

5407N **Fentanyl**, Lozenges 200 micrograms (as citrate), 30 (*Actiq*)(**Palliative Care**)

From:

5408P **Fentanyl**, Lozenges 400 micrograms (as citrate), 3 (*Actiq*)(**Palliative Care**)

To:

5408P **Fentanyl**, Lozenges 400 micrograms (as citrate), 30 (*Actiq*)(**Palliative Care**)

From:

5409Q **Fentanyl**, Lozenges 600 micrograms (as citrate), 3 (*Actiq*)(**Palliative Care**)

To:

5409Q **Fentanyl**, Lozenges 600 micrograms (as citrate), 30 (*Actiq*)(**Palliative Care**)

From:

5410R **Fentanyl**, Lozenges 800 micrograms (as citrate), 3 (*Actiq*)(**Palliative Care**)

To:

5410R **Fentanyl**, Lozenges 800 micrograms (as citrate), 30 (*Actiq*)(**Palliative Care**)

From:

5411T **Fentanyl**, Lozenges 1200 micrograms (as citrate), 3 (*Actiq*)(**Palliative Care**)

To:

5411T **Fentanyl**, Lozenges 1200 micrograms (as citrate), 30 (*Actiq*)(**Palliative Care**)

From:

5412W **Fentanyl**, Lozenges 1600 micrograms (as citrate), 3 (*Actiq*)(**Palliative Care**)

To:

5412W **Fentanyl**, Lozenges 1600 micrograms (as citrate), 30 (*Actiq*)(**Palliative Care**)

From:

2981X **Methylprednisolone Sodium Succinate**, Powder for injection equivalent to 40 mg methylprednisolone with diluent (*Solu-Medrol*)

To:

2981X **Methylprednisolone**, Powder for injection 40 mg (as sodium succinate) with diluent (*Solu-Medrol*)

From:

8834Y **Methylprednisolone Sodium Succinate**, Powder for injection equivalent to 1 g methylprednisolone with diluent (*Solu-Medrol*)

To:

8834Y **Methylprednisolone**, Powder for injection 1 g (as sodium succinate) with diluent (*Solu-Medrol*)

Alterations – Maximum Quantity

		From:	To:
5407N	Fentanyl , Lozenges 200 micrograms (as citrate), 30 (<i>Actiq</i>)(Palliative Care)	20	2
5408P	Fentanyl , Lozenges 400 micrograms (as citrate), 30 (<i>Actiq</i>)(Palliative Care)	20	2
5409Q	Fentanyl , Lozenges 600 micrograms (as citrate), 30 (<i>Actiq</i>)(Palliative Care)	20	2
5410R	Fentanyl , Lozenges 800 micrograms (as citrate), 30 (<i>Actiq</i>)(Palliative Care)	20	2
5411T	Fentanyl , Lozenges 1200 micrograms (as citrate), 30 (<i>Actiq</i>)(Palliative Care)	20	2
5412W	Fentanyl , Lozenges 1600 micrograms (as citrate), 30 (<i>Actiq</i>)(Palliative Care)	20	2

Alterations – Restriction

8986Y	Docetaxel , Solution concentrate for I.V. infusion 20 mg in 1 mL (<i>Taxotere, Oncotaxel 20</i>)
8987B	Docetaxel , Solution concentrate for I.V. infusion 20 mg in 2 mL (<i>DBL Docetaxel Concentrated Injection</i>)
8988C	Docetaxel , Injection set containing 1 single use vial concentrate for I.V. infusion 20 mg (anhydrous) in 0.5 mL with solvent (<i>Taxotere</i>)
8989D	Docetaxel , Solution concentrate for I.V. infusion 80 mg in 4 mL (<i>Taxotere, Oncotaxel 80</i>)
8990E	Docetaxel , Solution concentrate for I.V. infusion 80 mg in 8 mL (<i>DBL Docetaxel Concentrated Injection</i>)
8991F	Docetaxel , Injection set containing 1 single use vial concentrate for I.V. infusion 80 mg (anhydrous) in 2 mL with solvent (<i>Taxotere</i>)
8992G	Docetaxel , Solution concentrate for I.V. infusion 160 mg in 16 mL (<i>DBL Docetaxel Concentrated Injection</i>)
8374R	Leflunomide , Tablet 10 mg (<i>Arava, Arabloc, APO-Leflunomide, Lunava 10</i>)
8375T	Leflunomide , Tablet 20 mg (<i>Arava, Arabloc, APO-Leflunomide, Lunava 20</i>)

Alterations – Notes

9398P	Desmopressin Acetate , Wafer 120 micrograms (base) (<i>Minirin Melt</i>)
8878G	Fentanyl , Transdermal patch 2.1 mg (releasing approximately 12 micrograms per hour) (<i>Durogesic 12</i>)
8891Y	Fentanyl , Transdermal patch 4.2 mg (releasing approximately 25 micrograms per hour) (<i>Durogesic 25</i>)
8892B	Fentanyl , Transdermal patch 8.4 mg (releasing approximately 50 micrograms per hour) (<i>Durogesic 50</i>)
8893C	Fentanyl , Transdermal patch 12.6 mg (releasing approximately 75 micrograms per hour) (<i>Durogesic 75</i>)
8894D	Fentanyl , Transdermal patch 16.8 mg (releasing approximately 100 micrograms per hour) (<i>Durogesic 100</i>)

Alterations – Manufacturer's Code

		<i>From:</i>	<i>To:</i>
9366Y	<i>Pristiq, PF</i> – Desvenlafaxine Succinate , Tablet 50 mg (base) (extended release)	WX	PF
9367B	<i>Pristiq, PF</i> – Desvenlafaxine Succinate , Tablet 100 mg (base) (extended release)	WX	PF
3445H	<i>Enbrel, PF</i> – Etanercept , Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	WX	PF
3446J	<i>Enbrel, PF</i> – Etanercept , Injections 50 mg in 1 mL single use pre-filled syringes, 4	WX	PF
3447K	<i>Enbrel, PF</i> – Etanercept , Injection 50 mg in 1 mL single use auto-injector, 4	WX	PF
3448L	<i>Enbrel, PF</i> – Etanercept , Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	WX	PF
3449M	<i>Enbrel, PF</i> – Etanercept , Injections 50 mg in 1 mL single use pre-filled syringes, 4	WX	PF
3450N	<i>Enbrel, PF</i> – Etanercept , Injection 50 mg in 1 mL single use auto-injector, 4	WX	PF
8637N	<i>Enbrel, PF</i> – Etanercept , Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	WX	PF
8638P	<i>Enbrel, PF</i> – Etanercept , Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	WX	PF
8778B	<i>Enbrel, PF</i> – Etanercept , Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	WX	PF
8779C	<i>Enbrel, PF</i> – Etanercept , Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	WX	PF
9035M	<i>Enbrel, PF</i> – Etanercept , Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	WX	PF
9036N	<i>Enbrel, PF</i> – Etanercept , Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	WX	PF
9037P	<i>Enbrel, PF</i> – Etanercept , Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	WX	PF
9085E	<i>Enbrel, PF</i> – Etanercept , Injections 50 mg in 1 mL single use pre-filled syringes, 4	WX	PF
9086F	<i>Enbrel, PF</i> – Etanercept , Injections 50 mg in 1 mL single use pre-filled syringes, 4	WX	PF
9087G	<i>Enbrel, PF</i> – Etanercept , Injections 50 mg in 1 mL single use pre-filled syringes, 4	WX	PF
9088H	<i>Enbrel, PF</i> – Etanercept , Injections 50 mg in 1 mL single use pre-filled syringes, 4	WX	PF
9089J	<i>Enbrel, PF</i> – Etanercept , Injections 50 mg in 1 mL single use pre-filled syringes, 4	WX	PF
9090K	<i>Enbrel, PF</i> – Etanercept , Injections 50 mg in 1 mL single use pre-filled syringes, 4	WX	PF
9091L	<i>Enbrel, PF</i> – Etanercept , Injections 50 mg in 1 mL single use pre-filled syringes, 4	WX	PF
9429G	<i>Enbrel, PF</i> – Etanercept , Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	WX	PF
9431J	<i>Enbrel, PF</i> – Etanercept , Injections 50 mg in 1 mL single use pre-filled syringes, 4	WX	PF
9455P	<i>Enbrel, PF</i> – Etanercept , Injection 50 mg in 1 mL single use auto-injector, 4	WX	PF
9456Q	<i>Enbrel, PF</i> – Etanercept , Injection 50 mg in 1 mL single use auto-injector, 4	WX	PF
9457R	<i>Enbrel, PF</i> – Etanercept , Injection 50 mg in 1 mL single use auto-injector, 4	WX	PF
9458T	<i>Enbrel, PF</i> – Etanercept , Injection 50 mg in 1 mL single use auto-injector, 4	WX	PF
9459W	<i>Enbrel, PF</i> – Etanercept , Injection 50 mg in 1 mL single use auto-injector, 4	WX	PF
9460X	<i>Enbrel, PF</i> – Etanercept , Injection 50 mg in 1 mL single use auto-injector, 4	WX	PF
9461Y	<i>Enbrel, PF</i> – Etanercept , Injection 50 mg in 1 mL single use auto-injector, 4	WX	PF
9462B	<i>Enbrel, PF</i> – Etanercept , Injection 50 mg in 1 mL single use auto-injector, 4	WX	PF
3426H	<i>Simponi, JC</i> – Golimumab , Injection 50 mg in 0.5 mL single use pre-filled syringe	SH	JC
3427J	<i>Simponi, JC</i> – Golimumab , Injection 50 mg in 0.5 mL single use pre-filled pen	SH	JC

		From:	To:
3428K	<i>Simponi, JC</i> – Golimumab , Injection 50 mg in 0.5 mL single use pre-filled syringe	SH	JC
3429L	<i>Simponi, JC</i> – Golimumab , Injection 50 mg in 0.5 mL single use pre-filled pen	SH	JC
3430M	<i>Simponi, JC</i> – Golimumab , Injection 50 mg in 0.5 mL single use pre-filled syringe	SH	JC
3431N	<i>Simponi, JC</i> – Golimumab , Injection 50 mg in 0.5 mL single use pre-filled pen	SH	JC
3432P	<i>Simponi, JC</i> – Golimumab , Injection 50 mg in 0.5 mL single use pre-filled syringe	SH	JC
3433Q	<i>Simponi, JC</i> – Golimumab , Injection 50 mg in 0.5 mL single use pre-filled pen	SH	JC
3434R	<i>Simponi, JC</i> – Golimumab , Injection 50 mg in 0.5 mL single use pre-filled syringe	SH	JC
3435T	<i>Simponi, JC</i> – Golimumab , Injection 50 mg in 0.5 mL single use pre-filled pen	SH	JC
3436W	<i>Simponi, JC</i> – Golimumab , Injection 50 mg in 0.5 mL single use pre-filled syringe	SH	JC
3437X	<i>Simponi, JC</i> – Golimumab , Injection 50 mg in 0.5 mL single use pre-filled pen	SH	JC
5421H	<i>Aquae Gel, VT</i> – Hypromellose , Oral gel 20 mg per g, 100 g (Palliative Care)	HA	VT
5422J	<i>Aquae Gel, VT</i> – Hypromellose , Oral gel 20 mg per g, 100 g (Palliative Care)	HA	VT
9331D	<i>Zoton FasTabs, PF</i> – Lansoprazole , Tablet 15 mg (orally disintegrating)	WX	PF
9477T	<i>Zoton FasTabs, PF</i> – Lansoprazole , Tablet 30 mg (orally disintegrating)	WX	PF
9478W	<i>Zoton FasTabs, PF</i> – Lansoprazole , Tablet 30 mg (orally disintegrating)	WX	PF
1394J	<i>Monofeme 28, FZ</i> – Levonorgestrel with Ethinyloestradiol , Pack containing 21 tablets 150 micrograms-30 micrograms and 7 inert tablets	WX	FZ
1394J	<i>Nordette 28, PF</i> – Levonorgestrel with Ethinyloestradiol , Pack containing 21 tablets 150 micrograms-30 micrograms and 7 inert tablets	WY	PF
1392G	<i>Trifeme 28, FZ</i> – Levonorgestrel with Ethinyloestradiol , Pack containing 6 tablets 50 micrograms-30 micrograms, 5 tablets 75 micrograms-40 micrograms, 10 tablets 125 micrograms-30 micrograms and 7 inert tablets	WX	FZ
1392G	<i>Triphasil 28, PF</i> – Levonorgestrel with Ethinyloestradiol , Pack containing 6 tablets 50 micrograms-30 micrograms, 5 tablets 75 micrograms-40 micrograms, 10 tablets 125 micrograms-30 micrograms and 7 inert tablets	WY	PF
5423K	<i>Relistor, PF</i> – Methylnaltrexone , Solution for injection containing methylnaltrexone bromide 12 mg in 0.6 mL	WX	PF
5424L	<i>Relistor, PF</i> – Methylnaltrexone , Solution for injection containing methylnaltrexone bromide 12 mg in 0.6 mL	WX	PF
8694N	<i>Pizaccord, RA</i> – Pioglitazone , Tablet 15 mg (as hydrochloride)	MI	RA
8695P	<i>Pizaccord, RA</i> – Pioglitazone , Tablet 30 mg (as hydrochloride)	MI	RA
8696Q	<i>Pizaccord, RA</i> – Pioglitazone , Tablet 45 mg (as hydrochloride)	MI	RA
8724E	<i>Rapamune, PF</i> – Sirolimus , Tablet 1 mg	WX	PF
8833X	<i>Rapamune, PF</i> – Sirolimus , Tablet 2 mg	WX	PF
8725F	<i>Rapamune, PF</i> – Sirolimus , Oral solution 1 mg per mL, 60 mL	WX	PF
2285G	<i>Tinasil, AF</i> – Terbinafine , Tablet 250 mg (as hydrochloride)	AL	AF
2804N	<i>Tinasil, AF</i> – Terbinafine , Tablet 250 mg (as hydrochloride)	AL	AF
8301X	<i>Efexor-XR, PF</i> – Venlafaxine Hydrochloride , Capsule 75 mg (base) (modified release)	WX	PF
8302Y	<i>Efexor-XR, PF</i> – Venlafaxine Hydrochloride , Capsule 150 mg (base) (modified release)	WX	PF
8868R	<i>Efexor-XR, PF</i> – Venlafaxine Hydrochloride , Capsule 37.5 mg (base) (modified release)	WX	PF

SECTION 100 – HIGHLY SPECIALISED DRUGS PROGRAM

Additions

Additions – Items

5829T	Filgrastim , Injection 120 micrograms in 0.2 mL single use pre-filled syringe (<i>Nivestim</i>)(Public)
5830W	Filgrastim , Injection 120 micrograms in 0.2 mL single use pre-filled syringe (<i>Nivestim</i>)(Private)

Deletions

Deletions – Items

5723F	Epoetin Alfa , Injection 30,000 units in 0.75 mL pre-filled syringe (<i>Eprex 30,000</i>)(Public)
9623L	Epoetin Alfa , Injection 30,000 units in 0.75 mL pre-filled syringe (<i>Eprex 30,000</i>)(Private)

Alterations

Alterations – Manufacturer's Code

		<i>From:</i>	<i>To:</i>
5733R	<i>Enbrel, PF</i> – Etanercept , Injections 50 mg in 1 mL single use pre-filled syringes, 4 (Public)	WX	PF
5734T	<i>Enbrel, PF</i> – Etanercept , Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL (Public)	WX	PF
5735W	<i>Enbrel, PF</i> – Etanercept , Injection 50 mg in 1 mL single use auto-injector, 4 (Public)	WX	PF
6367D	<i>Enbrel, PF</i> – Etanercept , Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL (Private)	WX	PF
9615C	<i>Enbrel, PF</i> – Etanercept , Injections 50 mg in 1 mL single use pre-filled syringes, 4 (Private)	WX	PF
9641K	<i>Enbrel, PF</i> – Etanercept , Injection 50 mg in 1 mL single use auto-injector, 4 (Private)	WX	PF
5753T	<i>Remicade, JC</i> – Infliximab , Powder for I.V. infusion 100 mg (Public)	SH	JC
5754W	<i>Remicade, JC</i> – Infliximab , Powder for I.V. infusion 100 mg (Public)	SH	JC
5755X	<i>Remicade, JC</i> – Infliximab , Powder for I.V. infusion 100 mg (Public)	SH	JC
5756Y	<i>Remicade, JC</i> – Infliximab , Powder for I.V. infusion 100 mg (Public)	SH	JC
5757B	<i>Remicade, JC</i> – Infliximab , Powder for I.V. infusion 100 mg (Public)	SH	JC
5758C	<i>Remicade, JC</i> – Infliximab , Powder for I.V. infusion 100 mg (Public)	SH	JC
6397Q	<i>Remicade, JC</i> – Infliximab , Powder for I.V. infusion 100 mg (Private)	SH	JC
6448J	<i>Remicade, JC</i> – Infliximab , Powder for I.V. infusion 100 mg (Private)	SH	JC
6496X	<i>Remicade, JC</i> – Infliximab , Powder for I.V. infusion 100 mg (Private)	SH	JC
9612X	<i>Remicade, JC</i> – Infliximab , Powder for I.V. infusion 100 mg (Private)	SH	JC
9613Y	<i>Remicade, JC</i> – Infliximab , Powder for I.V. infusion 100 mg (Private)	SH	JC
9617E	<i>Remicade, JC</i> – Infliximab , Powder for I.V. infusion 100 mg (Private)	SH	JC
9654D	<i>Remicade, JC</i> – Infliximab , Powder for I.V. infusion 100 mg (Public)	SH	JC
9674E	<i>Remicade, JC</i> – Infliximab , Powder for I.V. infusion 100 mg (Private)	SH	JC
5792W	<i>Celsentri, VI</i> – Maraviroc , Tablet 150 mg (Public)	PF	VI
5793X	<i>Celsentri, VI</i> – Maraviroc , Tablet 300 mg (Public)	PF	VI
9572T	<i>Celsentri, VI</i> – Maraviroc , Tablet 150 mg (Private)	PF	VI
9573W	<i>Celsentri, VI</i> – Maraviroc , Tablet 300 mg (Private)	PF	VI
9549N	<i>Rapamune, PF</i> – Sirolimus , Tablet 1 mg (Public)	WX	PF
9548M	<i>Rapamune, PF</i> – Sirolimus , Tablet 2 mg (Public)	WX	PF
9550P	<i>Rapamune, PF</i> – Sirolimus , Oral solution 1 mg per mL, 60 mL (Public)	WX	PF
6436R	<i>Rapamune, PF</i> – Sirolimus , Tablet 1 mg (Private)	WX	PF

		<i>From:</i>	<i>To:</i>
6457W	<i>Rapamune, PF – Sirolimus</i> , Tablet 2 mg (Private)	WX	PF
6437T	<i>Rapamune, PF – Sirolimus</i> , Oral solution 1 mg per mL, 60 mL (Private)	WX	PF

SECTION 100 – HUMAN GROWTH HORMONE

Addition

Addition – Item

6310D **Somatropin (Recombinant human growth hormone)** , Injection 10 mg (30 i.u.) vial with diluent (with preservative)
(*Zomacton*)

Alteration

Alteration – Item Description

From:

6266T **Somatropin (Recombinant human growth hormone)** , Injection 4 mg (12 i.u.) vial with 3.5 mL diluent (with preservative)
(*Zomacton*)

To:

6266T **Somatropin (Recombinant human growth hormone)** , Injection 4 mg (12 i.u.) vial with diluent (with preservative)
(*Zomacton*)

REPATRIATION PHARMACEUTICAL BENEFITS

Deletions

Deletions – Items

4031E **Antazoline with Naphazoline**, Eye drops 5 mg (sulfate)-250 micrograms (nitrate) per mL (0.5%-0.025%), 10 mL (*Antistine-Privine*)

4659F **Bandage—retention—cohesive—heavy**, Bandage 7.5 cm x 3 m (*Coplus 3629*)

4772E **Gloves Plastic (disposable)**, Gloves, small, 100 (*Handy 4207*)

4773F **Gloves Plastic (disposable)**, Gloves, medium, 100 (*Handy 4208*)

4774G **Gloves Plastic (disposable)**, Gloves, large, 100 (*Handy 4209*)

Alterations

Alterations – Brand Name

From:

4717G *Handy 5608, BV – Bandage—calico*, Bandage, triangular, large

To:

4717G *Handy 36361414, BV – Bandage—calico*, Bandage, triangular, large

From:

4736G *Tensopress 66004347, BV – Bandage—compression*, Bandage, high stretch, 7.5 cm x 3 m

To:

4736G *Tensopress 71723-01, BV – Bandage—compression*, Bandage, high stretch, 7.5 cm x 3 m

From:

4748X *Tensopress 66004348, BV – Bandage—compression*, Bandage, high stretch, 10 cm x 3 m

To:

4748X *Tensopress 71723-00, BV – Bandage—compression*, Bandage, high stretch, 10 cm x 3 m
From:

4654Y *Comprilan 1027, BV – Bandage—compression*, Bandage, short stretch, 8 cm x 5 m
To:

4654Y *Comprilan 01027-00, BV – Bandage—compression*, Bandage, short stretch, 8 cm x 2.6 m
From:

4898T *Cutifilm Plus 76309, SN – Dressing—film island*, Dressings 5 cm x 7.2 cm, 5
To:

4898T *Cutifilm Plus 36361370, SN – Dressing—film island*, Dressings 5 cm x 7.2 cm, 5
From:

4899W *Cutifilm Plus 76308, SN – Dressing—film island*, Dressings 8 cm x 10 cm, 5
To:

4899W *Cutifilm Plus 36361371, SN – Dressing—film island*, Dressings 8 cm x 10 cm, 5
From:

4707R *Handy 5672, BV – Dressing—gauze (absorbent pad)*, Pads 5 cm x 5 cm, 100
To:

4707R *Handy 71117-05, BV – Dressing—gauze (absorbent pad)*, Pads 5 cm x 5 cm, 100
From:

4708T *Handy 5674, BV – Dressing—gauze (absorbent pad)*, Pads 10 cm x 10 cm, 100
To:

4708T *Handy 71117-06, BV – Dressing—gauze (absorbent pad)*, Pads 10 cm x 10 cm, 100
From:

4819P *Cutilin Non-Stick Wound Pad 76301, SN – Dressing—non-adherent*, Dressings 5 cm x 5 cm, 5
To:

4819P *Cutilin Non-Stick Wound Pad 36361374, SN – Dressing—non-adherent*, Dressings 5 cm x 5 cm, 5
From:

4862X *Cutilin Non-Stick Wound Pad 76300, SN – Dressing—non-adherent*, Dressings 10 cm x 10 cm, 5
To:

4862X *Cutilin Non-Stick Wound Pad 36361375, SN – Dressing—non-adherent*, Dressings 10 cm x 10 cm, 5
From:

4780N *Leukoplast 1071, BV – Tapes—plaster adhesive elastic*, Roll 2.5 cm x 2.5 m
To:

4780N *Leukoplast 01071-00, BV – Tapes—plaster adhesive elastic*, Roll 2.5 cm x 2.5 m
From:

4781P *Leukoplast 1072, BV – Tapes—plaster adhesive elastic*, Roll 5 cm x 2.5 m
To:

4781P *Leukoplast 01072-00, BV – Tapes—plaster adhesive elastic*, Roll 5 cm x 2.5 m
From:

4782Q *Leukoplast 1073, BV – Tapes—plaster adhesive elastic*, Roll 7.5 cm x 2.5 m
To:

4782Q *Leukoplast 01073-00, BV – Tapes—plaster adhesive elastic*, Roll 7.5 cm x 2.5 m

Alterations – Item Description

From:

4654Y **Bandage—compression**, Bandage, short stretch, 8 cm x 5 m (*Comprilan 1027*)

To:

4654Y **Bandage—compression**, Bandage, short stretch, 8 cm x 2.6 m (*Comprilan 01027-00*)

Alterations – Manufacturer's Code

		<i>From:</i>	<i>To:</i>
4284L	<i>Remicade, JC</i> – Infliximab , Powder for I.V. infusion 100 mg	SH	JC
4011D	<i>Tinasil, AF</i> – Terbinafine , Tablet 250 mg (as hydrochloride)	AL	AF

Advance Notices

Advance Notices – Deletion of Brands

The following brands will be deleted from the Schedule of Pharmaceutical Benefits on 1 September 2011:

Brand discontinued by the manufacturer —

1446D *Parlodel, NV* – **Bromocriptine Mesylate**, Capsule 5 mg (base)

1445C *Parlodel, NV* – **Bromocriptine Mesylate**, Capsule 10 mg (base)

The following brands will be deleted from the Schedule of Pharmaceutical Benefits on 1 October 2011:

Brands discontinued by the manufacturer—

2344J *Cardinorm, HX* – **Amiodarone**, Tablet containing amiodarone hydrochloride 100 mg

2343H *Cardinorm, HX* – **Amiodarone**, Tablet containing amiodarone hydrochloride 200 mg

8280T *Vinorelbine Link, FU* – **Vinorelbine**, Solution for I.V. infusion 10 mg (as tartrate) in 1 mL

8281W *Vinorelbine Link, FU* – **Vinorelbine**, Solution for I.V. infusion 50 mg (as tartrate) in 5 mL

The following brand will be deleted from the Schedule of Pharmaceutical Benefits on 1 November 2011:

Deletion requested by the manufacturer—

1357K *Prothiaden, AB* – **Dothiepin Hydrochloride**, Capsule 25 mg

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
3058Y NP,MW	CEPHALEXIN Capsule 250 mg	20	1	..	8.72	9.81	^a Cefalexin Sandoz SZ
							^a Cephalexin generichealth GQ
							^a Cephatrust 250 MI
							^a Chem mart Cephalexin CH
							^a Cilex GM
							^a GenRx Cephalexin GX
							^a Ialex LN
							^a Ibilex 250 AF
							^a Pharmacor Cephalexin 250 CR
							^a Rancef RA
							^a Terry White Chemists Cephalexin TW
							^a Keflex AS
							3119E NP,MW
^a Cephalexin generichealth GQ							
^a Cephatrust 500 MI							
^a Chem mart Cephalexin CH							
^a Cilex GM							
^a GenRx Cephalexin GX							
^a Ialex LN							
^a Ibilex 500 AF							
^a Pharmacor Cephalexin 500 CR							
^a Rancef RA							
^a Terry White Chemists Cephalexin TW							
^a Keflex AS							
				^B 3.14	11.86	9.81	
							^a Cephalexin Sandoz SZ
							^a Cephalexin Sandoz SZ
							^a Cephalexin generichealth GQ
							^a Cephatrust 500 MI
							^a Chem mart Cephalexin CH
							^a Cilex GM
							^a GenRx Cephalexin GX
							^a Ialex LN
							^a Ibilex 500 AF
							^a Pharmacor Cephalexin 500 CR
							^a Rancef RA
							^a Terry White Chemists Cephalexin TW
							^a Keflex AS
				^B 4.20	14.75	11.64	^a Keflex AS

DESMOPRESSIN ACETATE

Authority required (STREAMLINED)

2641

Primary nocturnal enuresis in patients aged 6 years or older who are refractory to an enuresis alarm;

2642

Primary nocturnal enuresis in patients aged 6 years or older for whom an enuresis alarm is contraindicated. The reason that an alarm is contraindicated must be documented in the patient's medical records when treatment is initiated.

Note

Not to be used in preference to enuresis alarms.

Desmopressin nasal spray may be associated with an increased risk of hyponatraemia compared to the oral formulations.

Note

Only one application per six months will be authorised for the wafers. No more than twice the maximum quantity for the 120 micrograms wafers and no applications for increased maximum quantities for the 240 micrograms wafers will be authorised.

8975J NP	Wafer 240 micrograms (base)	30	5	..	115.94	34.20	Minirin Melt	FP
9398P NP	Wafer 120 micrograms (base)	30	5	..	70.85	34.20	Minirin Melt	FP

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
DOCETAXEL							
<u>Authority required</u>							
Treatment of HER2 positive early breast cancer in combination with trastuzumab.							
<u>Note</u>							
The 20 mg solution concentrates for I.V. infusion and solution for I.V. infusion (after reconstitution) are bioequivalent.							
8986Y	Solution concentrate for I.V. infusion 20 mg in 1 mL	2	*651.16	34.20 ^a	Oncotaxel 20 TA
						^a	Taxotere SW
8987B	Solution concentrate for I.V. infusion 20 mg in 2 mL	2	*651.16	34.20 ^a	DBL Docetaxel Concentrated Injection HH
8988C	Injection set containing 1 single use vial concentrate for I.V. infusion 20 mg (anhydrous) in 0.5 mL with solvent	2	*651.16	34.20 ^a	Taxotere SW
<hr/>							
DOCETAXEL							
<u>Authority required</u>							
Treatment of HER2 positive early breast cancer in combination with trastuzumab.							
<u>Note</u>							
The 80 mg solution concentrates for I.V. infusion and solution for I.V. infusion (after reconstitution) are bioequivalent.							
8989D	Solution concentrate for I.V. infusion 80 mg in 4 mL	1	1280.83	34.20 ^a	Oncotaxel 80 TA
						^a	Taxotere SW
8990E	Solution concentrate for I.V. infusion 80 mg in 8 mL	1	1280.83	34.20 ^a	DBL Docetaxel Concentrated Injection HH
8991F	Injection set containing 1 single use vial concentrate for I.V. infusion 80 mg (anhydrous) in 2 mL with solvent	1	1280.83	34.20 ^a	Taxotere SW
<hr/>							
DOCETAXEL							
<u>Authority required</u>							
Treatment of HER2 positive early breast cancer in combination with trastuzumab.							
8992G	Solution concentrate for I.V. infusion 160 mg in 16 mL	1	2457.26	34.20	DBL Docetaxel Concentrated Injection HH
<hr/>							
DOCETAXEL							
<u>Authority required</u>							
Adjuvant treatment of operable breast cancer in combination with cyclophosphamide.							
<u>Note</u>							
A maximum of four cycles of treatment will be authorised under this restriction.							
<u>Note</u>							
The 20 mg solution concentrates for I.V. infusion and solution for I.V. infusion (after reconstitution) are bioequivalent.							
5270J	Solution concentrate for I.V. infusion 20 mg in 1 mL	2	*651.16	34.20 ^a	Oncotaxel 20 TA
						^a	Taxotere SW
5271K	Injection set containing 1 single use vial concentrate for I.V. infusion 20 mg (anhydrous) in 0.5 mL with solvent	2	*651.16	34.20 ^a	Taxotere SW
<hr/>							
DOCETAXEL							
<u>Authority required</u>							
Adjuvant treatment of operable breast cancer in combination with cyclophosphamide.							

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
Note							
A maximum of four cycles of treatment will be authorised under this restriction.							
Note							
The 80 mg solution concentrates for I.V. infusion and solution for I.V. infusion (after reconstitution) are bioequivalent.							
5272L	Solution concentrate for I.V. infusion 80 mg in 4 mL	1	1280.83	34.20 ^a	Oncotaxel 80 TA
						^a	Taxotere SW
5273M	Injection set containing 1 single use vial concentrate for I.V. infusion 80 mg (anhydrous) in 2 mL with solvent	1	1280.83	34.20 ^a	Taxotere SW
DUTASTERIDE with TAMSULOSIN							
Authority required (STREAMLINED)							
3687							
Treatment of lower urinary tract symptoms due to benign prostatic hyperplasia where treatment has been initiated by a urologist.							
Note							
Continuing Therapy Only:							
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
5490Y NP	Capsule containing dutasteride 500 micrograms with tamsulosin hydrochloride 400 micrograms	30	5	..	35.29	34.20	Duodart 500ug/400ug GK
EXEMESTANE							
Restricted benefit							
Treatment of hormone-dependent advanced breast cancer in post-menopausal women with disease progression following treatment with tamoxifen citrate;							
Treatment of hormone-dependent early breast cancer in post-menopausal women following a minimum of 2 years' treatment with tamoxifen citrate.							
Note							
This drug is not PBS-subsidised for primary prevention of breast cancer.							
This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer extended beyond 5 years, i.e. a patient who has received 2 years of tamoxifen therapy may only receive 3 years of PBS-subsidised treatment with exemestane.							
Note							
Shared Care Model:							
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
8506Q NP	Tablet 25 mg	30	5	..	152.38	34.20 ^a	Aromasin PF
						^a	Exaccord RA
FENTANYL							
Caution							
The risk of drug dependence is high.							
Restricted benefit							
Chronic severe disabling pain not responding to non-narcotic analgesics.							
Note							
Authorities for increased maximum quantities and/or repeats will be granted only for:							
(i) chronic severe disabling pain associated with proven malignant neoplasia; or							
(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or							
(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or							
(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.							

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price	Maximum	Brand Name and Manufacturer	
					for Max. Qty \$	Recordable Value for Safety Net \$		
	Note Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain, because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).							
8878G NP	Transdermal patch 2.1 mg (releasing approximately 12 micrograms per hour)	5	41.53	34.20	Durogesic 12	JC

FENTANYL

Caution

The risk of drug dependence is high.

Restricted benefit

Chronic severe disabling pain not responding to non-narcotic analgesics.

Note

Authorities for increased maximum quantities and/or repeats will be granted only for:

(i) chronic severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

Note

Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain, because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

Pharmaceutical benefits that have the form fentanyl transdermal patch 2.55 mg (releasing approximately 25 micrograms per hour) and pharmaceutical benefits that have the form fentanyl transdermal patch 4.2 mg (releasing approximately 25 micrograms per hour) are equivalent for the purposes of substitution.

5277R NP	Transdermal patch 2.55 mg (releasing approximately 25 micrograms per hour)	5	49.46	34.20 ^a	Denpax	AF
8891Y NP	Transdermal patch 4.2 mg (releasing approximately 25 micrograms per hour)	5	49.46	34.20 ^a	Durogesic 25	JC

FENTANYL

Caution

The risk of drug dependence is high.

Restricted benefit

Chronic severe disabling pain not responding to non-narcotic analgesics.

Note

Authorities for increased maximum quantities and/or repeats will be granted only for:

(i) chronic severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price	Maximum	Brand Name and Manufacturer
					for Max. Qty \$	Recordable Value for Safety Net \$	
Note							
Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain, because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).							
Pharmaceutical benefits that have the form fentanyl transdermal patch 5.10 mg (releasing approximately 50 micrograms per hour) and pharmaceutical benefits that have the form fentanyl transdermal patch 8.4 mg (releasing approximately 50 micrograms per hour) are equivalent for the purposes of substitution.							
5278T NP	Transdermal patch 5.10 mg (releasing approximately 50 micrograms per hour)	5	81.58	34.20 ^a	Denpax AF
8892B NP	Transdermal patch 8.4 mg (releasing approximately 50 micrograms per hour)	5	81.58	34.20 ^a	Durogesic 50 JC

FENTANYL

Caution

The risk of drug dependence is high.

Restricted benefit

Chronic severe disabling pain not responding to non-narcotic analgesics.

Note

Authorities for increased maximum quantities and/or repeats will be granted only for:

- (i) chronic severe disabling pain associated with proven malignant neoplasia; or
- (ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or
- (iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
- (iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

Note

Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain, because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

Pharmaceutical benefits that have the form fentanyl transdermal patch 7.65 mg (releasing approximately 75 micrograms per hour) and pharmaceutical benefits that have the form fentanyl transdermal patch 12.6 mg (releasing approximately 75 micrograms per hour) are equivalent for the purposes of substitution.

5279W NP	Transdermal patch 7.65 mg (releasing approximately 75 micrograms per hour)	5	108.37	34.20 ^a	Denpax AF
8893C NP	Transdermal patch 12.6 mg (releasing approximately 75 micrograms per hour)	5	108.37	34.20 ^a	Durogesic 75 JC

FENTANYL

Caution

The risk of drug dependence is high.

Restricted benefit

Chronic severe disabling pain not responding to non-narcotic analgesics.

Note

Authorities for increased maximum quantities and/or repeats will be granted only for:

- (i) chronic severe disabling pain associated with proven malignant neoplasia; or
- (ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or
- (iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price	Maximum	Brand Name and Manufacturer
					for Max. Qty \$	Recordable Value for Safety Net \$	

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

Note

Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain, because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

Pharmaceutical benefits that have the form fentanyl transdermal patch 10.20 mg (releasing approximately 100 micrograms per hour) and pharmaceutical benefits that have the form fentanyl transdermal patch 16.8 mg (releasing approximately 100 micrograms per hour) are equivalent for the purposes of substitution.

5280X NP	Transdermal patch 10.20 mg (releasing approximately 100 micrograms per hour)	5	132.30	34.20	^a Denpax	AF
8894D NP	Transdermal patch 16.8 mg (releasing approximately 100 micrograms per hour)	5	132.30	34.20	^a Durogesic 100	JC

LEFLUNOMIDE

Caution

Leflunomide is a category X drug and must not be given to pregnant women. Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out.

Authority required (STREAMLINED)

2644

Treatment of severe active rheumatoid arthritis where other disease modifying anti-rheumatic drugs (including methotrexate) are ineffective and/or inappropriate. Treatment must be initiated by a physician.

8374R	Tablet 10 mg	30	5	..	76.80	34.20	^a APO-Leflunomide	TX
							^a Arabloc	AV
							^a Arava	SW
							^a Lunava 10	ZP
8375T	Tablet 20 mg	30	5	..	113.57	34.20	^a APO-Leflunomide	TX
							^a Arabloc	AV
							^a Arava	SW
							^a Lunava 20	ZP

LEFLUNOMIDE

Caution

Leflunomide is a category X drug and must not be given to pregnant women. Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out.

Authority required (STREAMLINED)

2682

Treatment of severe active psoriatic arthritis where other disease modifying anti-rheumatic drugs (including methotrexate) are ineffective and/or inappropriate. Treatment must be initiated by a physician.

5449T	Tablet 10 mg	30	5	..	76.80	34.20	^a Arabloc	AV
							^a Arava	SW
5450W	Tablet 20 mg	30	5	..	113.57	34.20	^a Arabloc	AV
							^a Arava	SW

METHYLPREDNISOLONE

Note

Pharmaceutical benefits that have the form methylprednisolone powder for injection 40 mg (as sodium succinate) and pharmaceutical benefits that have the form methylprednisolone powder for injection 40 mg (as sodium succinate) with diluent are equivalent for the purposes of substitution.

5263B NP	Powder for injection 40 mg (as sodium succinate)	5	30.47	31.56	^a Methylpred	AS
2981X NP	Powder for injection 40 mg (as sodium succinate) with diluent	5	30.47	31.56	^a Solu-Medrol	PF

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	a	Brand Name and Manufacturer
METHYLPREDNISOLONE								
Note								
Pharmaceutical benefits that have the form methylprednisolone powder for injection 1 g (as sodium succinate) and pharmaceutical benefits that have the form methylprednisolone powder for injection 1 g (as sodium succinate) with diluent are equivalent for the purposes of substitution.								
5264C NP	Powder for injection 1 g (as sodium succinate)	1	79.69	34.20	a	Methylpred AS
8834Y NP	Powder for injection 1 g (as sodium succinate) with diluent	1	79.69	34.20	a	Solu-Medrol PF
SALBUTAMOL SULFATE								
3495Y NP	Oral pressurised inhalation 100 micrograms (base) per dose (200 doses), CFC-free formulation	1	10.12	11.21	a	Airomir IA
							a	APO-Salbutamol Inhaler TX
					10.77	11.86	a	Asmol CFC-free AL
							a	Ventolin CFC-free GK
8288F NP	Oral pressurised inhalation 100 micrograms (base) per dose (200 doses), CFC-free formulation	2	5	..	*13.82	14.91	a	Airomir IA
							a	APO-Salbutamol Inhaler TX
							a	Asmol CFC-free AL
				^B 1.30	*15.12	14.91	a	Ventolin CFC-free GK

**PREPARATIONS WHICH MAY BE PRESCRIBED FOR
PATIENTS RECEIVING PALLIATIVE CARE**

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
FENTANYL							
<u>Caution</u>							
The risk of drug dependence is high.							
<u>Authority required</u>							
Continuing supply for breakthrough pain in a palliative care patient with cancer who is receiving opioids for their persistent pain and where further escalation in the dose of morphine for breakthrough pain results in intolerable adverse effects.							
<u>Note</u>							
For first continuing supply, applications for increased repeats for up to 3 months' supply may be authorised.							
Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months' supply may be authorised.							
Telephone approvals are limited to 1 month's therapy.							
<u>Note</u>							
Shared Care Model:							
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
<u>Note</u>							
Special Pricing Arrangements apply.							
5407N NP	Lozenges 200 micrograms (as citrate), 30 (Palliative Care)	2	*680.13	34.20	Actiq OA
5408P NP	Lozenges 400 micrograms (as citrate), 30 (Palliative Care)	2	*680.13	34.20	Actiq OA
5409Q NP	Lozenges 600 micrograms (as citrate), 30 (Palliative Care)	2	*680.13	34.20	Actiq OA
5410R NP	Lozenges 800 micrograms (as citrate), 30 (Palliative Care)	2	*680.13	34.20	Actiq OA
5411T NP	Lozenges 1200 micrograms (as citrate), 30 (Palliative Care)	2	*680.13	34.20	Actiq OA
5412W NP	Lozenges 1600 micrograms (as citrate), 30 (Palliative Care)	2	*680.13	34.20	Actiq OA

**PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING
DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY**

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price	Maximum		Brand Name and Manufacturer
					for Max. Qty \$	Recordable Value for Safety Net \$		
3317N	CEPHALEXIN Capsule 250 mg (Dental)	20	8.72	9.81	a	Cefalexin Sandoz SZ
								a Cephalexin GQ
								a generichealth MI
								a Cephatrust 250 MI
								a Chem mart CH
								a Cephalexin CH
								a Cilex GM
								a GenRx Cephalexin GX
								a Ialex LN
								a Ibilex 250 AF
								a Pharmacor CR
								a Cephalexin 250 CR
								a Rancef RA
a Terry White TW								
								a Chemists Cephalexin
3318P	Capsule 500 mg (Dental)	20	10.55	11.64	a	Cefalexin Sandoz SZ
								a Cephalexin AS
								a Keflex AS
								a Cephalexin BF
								a generichealth GQ
								a Cephatrust 500 MI
								a Chem mart CH
								a Cephalexin CH
								a Cilex GM
								a GenRx Cephalexin GX
								a Ialex LN
								a Ibilex 500 AF
								a Pharmacor CR
a Cephalexin 500 CR								
a Rancef RA								
a Terry White TW								
								a Chemists Cephalexin
				^B 4.20	14.75	11.64	a	Keflex AS

HIGHLY SPECIALISED DRUGS PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
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ETANERCEPT

Note

Any queries concerning the arrangements to prescribe etanercept may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe etanercept should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and etanercept for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in the following NOTES and restrictions, it refers to adalimumab and etanercept only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 bDMARDs at any 1 time.

From 1 November 2010, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to the alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, and
- fail to respond, or to sustain a response to one PBS-subsidised bDMARD twice and the other PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 November 2010 is considered to be in their first cycle as of 1 November 2010. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 November 2010, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 November 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

HIGHLY SPECIALISED DRUGS PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
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For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to the alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial the alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug twice within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.

A patient who commenced treatment with adalimumab for severe active juvenile idiopathic arthritis prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 12 month break in PBS-subsidised therapy' above for further details.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to Medicare Australia at the time treatment is ceased.

Authority required

Initial 1 (new patient or patient recommencing after a break of more than 12 months).

HIGHLY SPECIALISED DRUGS PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
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Initial treatment by a paediatric rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of a patient under 18 years:

- (a) who has severe active juvenile idiopathic arthritis; AND
- (b) whose parent or authorised guardian has signed a patient acknowledgement; AND
- (c) who has not received PBS-subsidised treatment with adalimumab or etanercept for this condition in the previous 12 months; AND
- (d) who has demonstrated either:
 - (i) severe intolerance of, or toxicity due to, methotrexate (see below for definition of severe intolerance and toxicity); or
 - (ii) failure to achieve an adequate response to 1 or more of the following treatment regimens:
 - oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or
 - oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other DMARD, alone or in combination with corticosteroids, for a minimum of 3 months. (Note: use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.)

Severe intolerance is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant NSAIDs on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, please provide details at time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of this toxicity at the time of application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- (a) an active joint count of at least 20 active (swollen and tender) joints; OR
- (b) at least 4 active joints from the following list:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment should be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
- (3) an acknowledgement signed by a parent or authorised guardian.

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 4 weeks from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to treatment 3 times (twice with one agent and once with the other) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial etanercept after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.

Authority required

Initial 2 (change or re-commencement after break of less than 12 months).

Initial PBS-subsidised treatment with etanercept by a paediatric rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of a patient under 18 years who:

- (a) has a documented history of severe active juvenile idiopathic arthritis; and
- (b) in this treatment cycle, has received prior PBS-subsidised treatment with adalimumab or etanercept for this condition; and
- (c) has not failed PBS-subsidised therapy with etanercept for this condition more than once in the current treatment cycle.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
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(b) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for a patient who has received PBS-subsidised treatment with etanercept in this treatment cycle and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised etanercept treatment, within the timeframes specified below.

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with etanercept may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised etanercept treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised etanercept treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to that particular course of bDMARD.

If a patient fails to respond to treatment 3 times (twice with one agent and once with the other) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial etanercept after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.

Authority required

Continuing treatment.

Continuing PBS-subsidised treatment with etanercept, by a rheumatologist or under the supervision of a paediatric rheumatology treatment centre, of a patient:

- (a) who has a documented history of severe active juvenile idiopathic arthritis; and
- (b) who has demonstrated an adequate response to treatment with etanercept; and
- (c) whose most recent course of PBS-subsidised bDMARD treatment in this treatment cycle was with etanercept.

An adequate response to treatment is defined as:

- (i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (ii) a reduction in the number of the following active joints, from at least 4, by at least 50%:
 - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

All applications for continuing treatment with etanercept must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

If a patient fails to respond to treatment 3 times (twice with one agent and once with the other) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial etanercept after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.

5734T	Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL (Public)	1	815.00	Enbrel	PF
6367D	Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL (Private)	1	854.02	Enbrel	PF

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ETANERCEPT

Note

Any queries concerning the arrangements to prescribe etanercept may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe etanercept should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and etanercept for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in the following NOTES and restrictions, it refers to adalimumab and etanercept only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 bDMARDs at any 1 time.

From 1 November 2010, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to the alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, and
- fail to respond, or to sustain a response to one PBS-subsidised bDMARD twice and the other PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 November 2010 is considered to be in their first cycle as of 1 November 2010. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 November 2010, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 November 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

HIGHLY SPECIALISED DRUGS PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
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For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to the alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial the alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug twice within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.

A patient who commenced treatment with adalimumab for severe active juvenile idiopathic arthritis prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 12 month break in PBS-subsidised therapy' above for further details.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to Medicare Australia at the time treatment is ceased.

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
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Authority required

Continuing treatment.

Continuing PBS-subsidised treatment with etanercept, by a rheumatologist or under the supervision of a paediatric rheumatology treatment centre, of a patient 18 years or older:

- (a) who has a documented history of severe active juvenile idiopathic arthritis; and
- (b) who has demonstrated an adequate response to treatment with etanercept; and
- (c) whose most recent course of PBS-subsidised bDMARD treatment in this treatment cycle was with etanercept.

An adequate response to treatment is defined as:

- (i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (ii) a reduction in the number of the following active joints, from at least 4, by at least 50%:
 - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

All applications for continuing treatment with etanercept must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

If a patient fails to respond to treatment 3 times (twice with one agent and once with the other) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

Where a patient with severe active juvenile idiopathic arthritis continues treatment with etanercept and is 18 years or older, etanercept 50 mg may be prescribed.

5733R	Injections 50 mg in 1 mL single use pre-filled syringes, 4 (Public)	1	1630.01	Enbrel	PF
5735W	Injection 50 mg in 1 mL single use auto-injector, 4 (Public)	1	1630.01	Enbrel	PF
9615C	Injections 50 mg in 1 mL single use pre-filled syringes, 4 (Private)	1	1676.43	Enbrel	PF
9641K	Injection 50 mg in 1 mL single use auto-injector, 4 (Private)	1	1676.43	Enbrel	PF

FILGRASTIM

Authority required (STREAMLINED)

3357

For use in a patient undergoing induction and consolidation therapy for acute myeloid leukaemia;

3358

Mobilisation of peripheral blood progenitor cells to facilitate harvest of such cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy;

3359

Mobilisation of peripheral blood progenitor cells, in a normal volunteer, for use in allogeneic transplantation;

3360

A patient receiving marrow-ablative chemotherapy and subsequent bone marrow transplantation;

3361

A patient with a non-myeloid malignancy receiving marrow-ablative chemotherapy and subsequent autologous peripheral blood progenitor cell transplantation;

3362

A patient with breast cancer receiving standard dose adjuvant chemotherapy who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;

HIGHLY SPECIALISED DRUGS PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max. Qty	\$	
	3363 A patient receiving chemotherapy for B-cell chronic lymphocytic leukaemia with fludarabine and cyclophosphamide who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;						
	3364 A patient receiving first-line chemotherapy for Hodgkin disease who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;						
	3365 A patient receiving chemotherapy for myeloma who has had a prior episode of febrile neutropenia, and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;						
	3366 A patient with severe congenital neutropenia (absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, and in whom a bone marrow examination has shown evidence of maturational arrest of the neutrophil lineage);						
	3367 A patient with severe chronic neutropenia (absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, or evidence of neutrophil dysfunction, and, either having experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months, or having recurrent clinically significant infections (a minimum of 3 in the previous 12 months));						
	3368 A patient with chronic cyclic neutropenia (absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, and, either having experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics, or having recurrent clinically significant infections (a minimum of 3 in the previous 12 months));						
	3369 A patient with inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned.						
	<u>Authority required (STREAMLINED)</u>						
	3370 A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia;						
	3371 A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in breast cancer (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide);						
	3372 A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours;						
	3373 A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in infants and children with CNS tumours;						
	3374 A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma;						
	3375 A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen);						
	3376 A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease;						
	3377 A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma.						
5829T	Injection 120 micrograms in 0.2 mL single use pre-filled syringe (Public)	20	11	..	*1006.22		Nivestim HH

FILGRASTIM

Authority required

For use in a patient undergoing induction and consolidation therapy for acute myeloid leukaemia;

HIGHLY SPECIALISED DRUGS PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	Mobilisation of peripheral blood progenitor cells to facilitate harvest of such cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy;					
	Mobilisation of peripheral blood progenitor cells, in a normal volunteer, for use in allogeneic transplantation;					
	A patient receiving marrow-ablative chemotherapy and subsequent bone marrow transplantation;					
	A patient with a non-myeloid malignancy receiving marrow-ablative chemotherapy and subsequent autologous peripheral blood progenitor cell transplantation;					
	A patient with breast cancer receiving standard dose adjuvant chemotherapy who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;					
	A patient receiving chemotherapy for B-cell chronic lymphocytic leukaemia with fludarabine and cyclophosphamide who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;					
	A patient receiving first-line chemotherapy for Hodgkin disease who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;					
	A patient receiving chemotherapy for myeloma who has had a prior episode of febrile neutropenia, and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;					
	A patient with severe congenital neutropenia (absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, and in whom a bone marrow examination has shown evidence of maturational arrest of the neutrophil lineage);					
	A patient with severe chronic neutropenia (absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, or evidence of neutrophil dysfunction, and, either having experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months, or having recurrent clinically significant infections (a minimum of 3 in the previous 12 months));					
	A patient with chronic cyclic neutropenia (absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, and, either having experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics, or having recurrent clinically significant infections (a minimum of 3 in the previous 12 months));					
	A patient with inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned.					
	<u>Authority required</u>					
	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia;					
	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in breast cancer (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide);					
	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours;					
	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in infants and children with CNS tumours;					
	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma;					
	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen);					
	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease;					
	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma.					
5830W	Injection 120 micrograms in 0.2 mL single use pre-filled syringe (Private)	20	11	..	*1052.64	Nivestim HH

INFLIXIMAB

Note

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

HIGHLY SPECIALISED DRUGS PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
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Medicare Australia
 Prior Written Approval of Specialised Drugs
 Reply Paid 9826
 GPO Box 9826
 HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab, etanercept, golimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 4 TNF-alfa antagonists at any 1 time.

From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised TNF-alfa antagonists without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and 18 weeks of treatment for infliximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of

HIGHLY SPECIALISED DRUGS PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
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continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap to an alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with golimumab.

A patient who commenced treatment with golimumab for active ankylosing spondylitis prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with golimumab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with golimumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Authority required

Initial 1 (new patients)

Initial PBS-subsidised treatment with infliximab, by a rheumatologist, of an adult with active ankylosing spondylitis who has radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis and who has not received any PBS-subsidised treatment with either adalimumab, etanercept, golimumab or infliximab in this treatment cycle; AND

(a) who has at least 2 of the following:

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
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- (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or
- (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI) [for further information on the BASMI please refer to the Medicare Australia website at www.medicareaustralia.gov.au]; or
- (iii) limitation of chest expansion relative to normal values for age and gender [for chest expansion normal values please refer to the Medicare Australia website at www.medicareaustralia.gov.au]; AND
- (b) who has failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Medicare Australia website at www.medicareaustralia.gov.au.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

- (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND
- (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Authority applications must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au] which must include the following:
 - (i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
 - (ii) a completed BASDAI Assessment Form [www.medicareaustralia.gov.au]; and
 - (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and
 - (iv) a signed patient acknowledgment form.

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 18 weeks of treatment with infliximab will be approved under this criterion.

At the time of the authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 18 weeks of treatment may be requested by telephone.

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial infliximab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised TNF-alfa antagonist was approved in this cycle and the date of the first application under a new cycle.

Authority required

Initial 2 (change or re-commencement for all patients)

Initial PBS-subsidised treatment with infliximab, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who, in this treatment cycle, has received prior PBS-subsidised TNF-alfa antagonist treatment for this condition and is eligible to receive further TNF-alfa antagonist therapy, and has not failed PBS-subsidised therapy with infliximab in the current treatment cycle.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised TNF-alfa antagonist therapy or, under this restriction, for patients who have received previous PBS-subsidised TNF-alfa antagonist therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to Medicare Australia no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

HIGHLY SPECIALISED DRUGS PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
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Where the most recent course of PBS-subsidised infliximab treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Authority applications must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au].

A maximum of 18 weeks of treatment with infliximab will be approved under this criterion.

At the time of the authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 18 weeks of treatment may be requested by telephone.

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial infliximab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised TNF-alfa antagonist was approved in this cycle and the date of the first application under a new cycle.

Authority required

Continuing treatment for all patients

Continuing PBS-subsidised treatment, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who:

- (a) has demonstrated an adequate response to treatment with infliximab; and
- (b) whose most recent course of PBS-subsidised therapy in this treatment cycle was with infliximab.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

Authority applications must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au].

All measurements provided must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with infliximab will be authorised under this criterion.

At the time of the authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone.

All applications for continuing treatment with infliximab must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with infliximab. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial infliximab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised TNF-alfa antagonist was approved in this cycle and the date of the first application under a new cycle.

5753T	Powder for I.V. infusion 100 mg (Public)	1	751.70	Remicade	JC
6448J	Powder for I.V. infusion 100 mg (Private)	1	788.19	Remicade	JC

INFLIXIMAB

Note

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

HIGHLY SPECIALISED DRUGS PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
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Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

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Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Rituximab patients:

A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

Note

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline

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measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

(4) Patients 'grandfathered' onto PBS-subsidised treatment with certolizumab pegol, golimumab or tocilizumab.

From 1 August 2010, a patient who commenced treatment with certolizumab pegol or golimumab for severe rheumatoid arthritis prior to 1 March 2010 or tocilizumab for severe rheumatoid arthritis prior to 1 July 2009 and who was 'grandfathered' on to PBS-subsidised therapy, and who continues to receive treatment will have further applications for treatment with certolizumab pegol, golimumab or tocilizumab assessed under the continuing treatment restriction.

A patient may only qualify for PBS-subsidised treatment under the grandfather restriction (Initial 3 ('grandfather patients')) once. A maximum of 24 weeks of treatment with certolizumab pegol, golimumab or tocilizumab will be authorised under this restriction.

Authority required

Initial 1 (new patient or patient re-commencing after a break of more than 24 months)

Initial PBS-subsidised treatment with infliximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

- (a) have severe active rheumatoid arthritis; and
- (b) have received no PBS-subsidised treatment with a bDMARD for this condition in the previous 24 months; and
- (c) have failed, in the 24 months immediately prior to the date of application, to achieve an adequate response to at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs), which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be:
 - hydroxychloroquine at a dose of at least 200 mg daily; or
 - leflunomide at a dose of at least 10 mg daily; or
 - sulfasalazine at a dose of at least 2 g daily.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, then the 6 months of intensive DMARD treatment must include at least 3 months continuous treatment with each of at least 2 of the DMARDs:

- hydroxychloroquine at a dose of at least 200 mg daily; and/or
- leflunomide at a dose of at least 10 mg daily; and/or
- sulfasalazine at a dose of at least 2 g daily.

The application must include details of the contraindication or intolerance to methotrexate. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

If 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved product information or cannot be tolerated at the doses specified above, then one or more of the following DMARDs may be used in place of these agents in order to satisfy the requirement for a trial of 6 months of intensive DMARD therapy with at least 2 DMARDs taken continuously for at least 3 months each:

- azathioprine at a dose of at least 1 mg/kg per day; and/or
- cyclosporin at a dose of at least 2 mg/kg/day; and/or
- sodium aurothiomalate at a dose of 50 mg weekly.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. Details of the toxicities, including severity, which will be accepted as a reason for substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy can be found on the

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Medicare Australia website [www.medicareaustralia.gov.au].

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

- (i) a total active joint count of at least 20 active (swollen and tender) joints; or
- (ii) at least 4 active joints from the following list of major joints:
 - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
- (3) a signed patient acknowledgement.

A maximum of 22 weeks of treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 3 mg per kg. Up to a maximum of 3 repeats may be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Authority required

Initial 2 (change or re-commencement after break of less than 24 months)

Initial course of PBS-subsidised treatment with infliximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

- (a) have a documented history of severe active rheumatoid arthritis; and
- (b) have received prior PBS-subsidised bDMARD treatment for this condition and are eligible to receive further bDMARD therapy.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for patients who have received PBS-subsidised treatment with infliximab and who wish to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised infliximab treatment, within the timeframes specified below.

A maximum of 22 weeks of treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 3 mg per kg. Up to a maximum of 3 repeats may be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST

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Monday to Friday).

Where the most recent course of PBS-subsidised infliximab treatment was approved under either of the initial 1 or 2 treatment restrictions, patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised infliximab treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Authority required

Continuing treatment

Continuing PBS-subsidised treatment with infliximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:

- (a) who have a documented history of severe active rheumatoid arthritis; and
- (b) who have demonstrated an adequate response to treatment with infliximab; and
- (c) whose most recent course of PBS-subsidised bDMARD treatment was with infliximab.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
AND either of the following:

- (i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
 - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 3 mg per kg. Up to a maximum of 2 repeats may be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

All applications for continuing treatment with infliximab must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note

Special Pricing Arrangements apply.

5757B	Powder for I.V. infusion 100 mg (Public)	1	751.70	Remicade	JC
6397Q	Powder for I.V. infusion 100 mg (Private)	1	788.19	Remicade	JC

INFLIXIMAB

Note

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

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Medicare Australia
 Prior Written Approval of Specialised Drugs
 Reply Paid 9826
 GPO Box 9826
 HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents (adalimumab, etanercept, golimumab and infliximab) for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, golimumab and infliximab.

From 1 August 2006, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The 5-year break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis after 1 August 2010.

(1) Initial treatment.

Applications for initial treatment should be made where:

- (i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
- (ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
- (iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for all agents except for infliximab, for which a maximum of 22 weeks will be authorised. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients — golimumab only.

Applications for patients who commenced treatment with golimumab prior to 1 March 2010 may apply for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

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Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
- (ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialed it on the PBS; or
- (iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a treatment Cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must re-qualify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Authority required

Initial 1

Initial PBS-subsidised treatment with infliximab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:

- (1) have severe active psoriatic arthritis; and
- (2) have received no prior PBS-subsidised biological treatment for this condition in this Treatment Cycle; and
- (3) have failed to achieve an adequate response to:
 - (a) methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; and
 - (b) sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; or
 - (c) leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please

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provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities, including severity, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(i) an active joint count of at least 20 active (swollen and tender) joints; or

(ii) at least 4 active joints from the following list of major joints:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(3) a signed patient acknowledgement.

A maximum of 22 weeks treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle. Patients may re-trial infliximab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Authority required

Initial 2

Initial PBS-subsidised treatment with infliximab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:

(1) have a documented history of severe active psoriatic arthritis; and

(2) have received prior PBS-subsidised biological treatment for this condition in this Treatment Cycle and are eligible to receive further biological therapy; and

(3) have not failed treatment with infliximab during the current Treatment Cycle.

Applications for patients who have received PBS-subsidised treatment with infliximab within this Treatment Cycle and who wish to re-commence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised infliximab treatment, within the timeframes specified below.

A maximum of 22 weeks treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised infliximab treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised infliximab treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

HIGHLY SPECIALISED DRUGS PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
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The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle. Patients may re-trial infliximab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Authority required

Continuing treatment

Continuing PBS-subsidised treatment with infliximab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults:

- (1) who have a documented history of severe active psoriatic arthritis; and
- (2) whose most recent course of PBS-subsidised biological agent for this condition in the current Treatment Cycle was with infliximab; and
- (3) who, at the time of application, demonstrate an adequate response to treatment with infliximab.

An adequate response to treatment with infliximab is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following:

- (i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
 - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats may be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

All applications for continuing treatment with infliximab must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle. Patients may re-trial infliximab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents (adalimumab, etanercept, golimumab and infliximab) for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, golimumab and infliximab.

From 1 August 2006, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
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The 5-year break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis after 1 August 2010.

(1) Initial treatment.

Applications for initial treatment should be made where:

- (i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
- (ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
- (iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for all agents except for infliximab, for which a maximum of 22 weeks will be authorised. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients — golimumab only.

Applications for patients who commenced treatment with golimumab prior to 1 March 2010 may apply for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
- (ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialed it on the PBS; or
- (iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
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To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a treatment Cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must re-qualify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

5756Y	Powder for I.V. infusion 100 mg (Public)	1	751.70	Remicade	JC
6496X	Powder for I.V. infusion 100 mg (Private)	1	788.19	Remicade	JC

INFLIXIMAB

Note

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for adult patients with severe refractory Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 August 2008, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 August 2008 is considered to be in their first cycle as of 1 August 2008.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

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Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2008.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2008, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, evidence of intestinal inflammation), or the prior corticosteroid therapy and immunosuppressive therapy.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

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To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 9 November 2007 or infliximab prior to 7 March 2007 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Authority required

Initial 1 (new patients)

Initial treatment of Crohn disease in a patient assessed by CDAI.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with severe refractory Crohn disease who satisfies the following criteria:

- (a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and
- (b) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
- (c) has failed to achieve an adequate response to prior systemic therapy including:
 - (i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and
 - (ii) immunosuppressive therapy including:
 - azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
 - 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or
 - methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

- (a) have a severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as assessed.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most

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recent prior treatment.

The most recent CDAI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 - (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition; and
 - (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
 - (iii) the signed patient acknowledgement.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A CDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Authority required

Initial 2

Change or re-commencement of treatment of Crohn disease in a patient assessed by CDAI.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below of a patient who:

- (a) has a documented history of severe refractory Crohn disease; and
- (b) in this treatment cycle, has received prior PBS-subsidised treatment with infliximab or adalimumab for this condition; and
- (c) has not failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 - (i) the completed current Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition; and
 - (ii) details of prior TNF alfa antagonist treatment including details of date and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed Price for		Brand Name and Manufacturer
					Max. Qty	\$	

A CDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Authority required

Continuing treatment of Crohn disease in a patient assessed by CDAI.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

- (a) has a documented history of severe refractory Crohn disease; and
- (b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 - (i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition.

The CDAI assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, a CDAI assessment of the patient's response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Initial 1

Initial treatment of Crohn disease in a patient with short gut syndrome or an ostomy patient.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist, or consultant physician as specified in the NOTE below of a patient who satisfies the following criteria:

- (a) has confirmed Crohn disease defined by standard clinical, endoscopic and/or imaging features, including histological evidence with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and
- (b) has diagnostic imaging or surgical evidence of short gut syndrome or has an ileostomy or colostomy; and
- (c) has evidence of intestinal inflammation; and
- (d) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
- (e) has failed to achieve an adequate response to prior systemic drug therapy including:
 - (i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and
 - (ii) immunosuppressive therapy including:
 - azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
 - 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or
 - methotrexate at a dose of at least 15 mg weekly for 3 or more months.

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NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) have evidence of intestinal inflammation, including:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; AND/OR

(ii) faeces: higher than normal lactoferrin or calprotectin level; AND/OR

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery;

AND/OR

(b) be assessed clinically as being in a high faecal output state;

AND/OR

(c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of infliximab.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(ii) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and

(iii) date of the most recent clinical assessment; and

(iv) the signed patient acknowledgement.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Authority required

Initial 2

Change or re-commencement of treatment of Crohn disease in a patient with short gut syndrome, an ostomy patient or a patient with extensive small intestine disease.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below of a patient who:

(a) has a documented history of severe refractory Crohn disease; and

(b) in this treatment cycle, has received prior PBS-subsidised treatment with infliximab or adalimumab for this condition; and

(c) has not failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle.

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NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 - (i) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criteria, if relevant; and
 - (ii) details of prior TNF alfa antagonist treatment including details of date and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Authority required

Continuing treatment of Crohn disease in a patient with short gut syndrome or an ostomy patient.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

- (a) has a documented history of severe refractory Crohn disease with intestinal inflammation and with short gut syndrome or with an ileostomy or colostomy; and
- (b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as:

- (a) improvement of intestinal inflammation as demonstrated by:
 - (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR
 - (ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR
 - (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or
- (b) reversal of high faecal output state; or
- (c) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 - (i) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy or the date of clinical assessment.

The patient's assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, an assessment of the patient's response to this initial course of

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treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Initial 1

Initial treatment of Crohn disease in a patient with extensive small intestine disease.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with severe refractory Crohn disease who satisfies the following criteria:

- (a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and
- (b) has extensive small intestinal disease with radiological evidence of intestinal inflammation affecting more than 50 cm of the small intestine; and
- (c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
- (d) has failed to achieve an adequate response to prior systemic therapy including:
 - (i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and
 - (ii) immunosuppressive therapy including:
 - azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
 - 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or
 - methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

- (a) have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; AND/OR
- (b) have evidence of active intestinal inflammation, including:
 - (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; AND/OR
 - (ii) faeces: higher than normal lactoferrin or calprotectin level; AND/OR
 - (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery; AND/OR
- (c) be assessed clinically as being in a high faecal output state; AND/OR
- (d) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of infliximab.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

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Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 - (i) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
 - (ii) (1) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; or
 - (2) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the dates of assessment of the patient's condition, if relevant; and
 - (iii) date of the most recent clinical assessment; and
 - (iv) the signed patient acknowledgement.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Authority required

Continuing treatment of Crohn disease in a patient with extensive small intestine disease.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, or consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

- (a) has a documented history of severe refractory Crohn disease with extensive intestinal inflammation affecting more than 50 cm of the small intestine; and
- (b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as:

- (a) a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150; or
- (b) improvement of intestinal inflammation as demonstrated by:
 - (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR
 - (ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR
 - (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or
 - (c) reversal of high faecal output state; or
 - (d) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 - (i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition; or
 - (ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy; or
 - (iii) the date of clinical assessment.

All assessments must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, an assessment of the patient's response must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those

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patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Initial 3 (grandfather)

Initial PBS-subsidised treatment of Crohn disease in a patient assessed by CDAI who has previously received non-PBS-subsidised therapy with infliximab.

Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who:

- (a) has a documented history of severe refractory Crohn disease and was receiving treatment with infliximab prior to 7 March 2007; and
- (b) had a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 prior to commencing treatment with infliximab. Where a baseline CDAI assessment is not available, please call Medicare Australia on 1800 700 270 to discuss; and
- (c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
- (d) has demonstrated or sustained an adequate response to treatment with infliximab. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 - (i) the completed current and baseline Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition; and
 - (ii) the signed patient acknowledgement.

The current CDAI assessment must be no more than 1 month old at the time of application. The baseline CDAI assessment must be from immediately prior to commencing treatment with infliximab.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only.

Authority required

Initial 3

Initial PBS-subsidised treatment of Crohn disease in a patient with short gut syndrome, an ostomy patient, or a patient with extensive small intestine disease, who has previously received non-PBS-subsidised therapy with infliximab.

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Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist, of a patient who:

- (a) has a documented history of severe refractory Crohn disease and was receiving treatment with infliximab prior to 7 March 2007; and
- (b) (1) has a history of extensive small intestinal disease with radiological evidence of intestinal inflammation affecting more than 50 cm of the small intestine; or
- (2) has diagnostic imaging or surgical evidence of short gut syndrome or has an ileostomy or colostomy with a documented history of intestinal inflammation; and
- (c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
- (d) has demonstrated or sustained an adequate response to treatment with infliximab according to the criteria included in the relevant continuation restriction. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

The same criteria used to determine an inadequate response to prior treatment at baseline must be used to determine response to treatment and eligibility for continuing therapy, according to the criteria included in the continuing treatment restriction.

An adequate response to infliximab treatment is defined as:

- (a) a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150; or
- (b) improvement of intestinal inflammation as demonstrated by:
 - (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR
 - (ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR
 - (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or
- (c) reversal of high faecal output state; or
- (d) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 - (i) (1) the completed current and baseline Crohn Disease Activity Index (CDAI) Score calculation sheet, where relevant, including the date of the assessment of the patient's condition; or
 - (2) the reports and dates of the current and baseline pathology or diagnostic imaging test(s) in order to assess response to therapy; or
 - (3) the date of clinical assessment(s); and
 - (ii) the signed patient acknowledgement.

The patient's assessment must be no more than 1 month old at the time of application. The baseline CDAI assessments must be from immediately prior to commencing treatment with infliximab. Where a baseline assessment is not available, please call Medicare Australia on 1800 700 270 to discuss.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only.

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for adult patients with severe refractory Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

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A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 August 2008, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 August 2008 is considered to be in their first cycle as of 1 August 2008.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2008.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2008, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

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(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, evidence of intestinal inflammation), or the prior corticosteroid therapy and immunosuppressive therapy.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 9 November 2007 or infliximab prior to 7 March 2007 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

5754W	Powder for I.V. infusion 100 mg (Public)	1	751.70	Remicade	JC
9613Y	Powder for I.V. infusion 100 mg (Private)	1	788.19	Remicade	JC

INFLIXIMAB

Note

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826

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HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for adult patients with severe refractory Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 August 2008, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 August 2008 is considered to be in their first cycle as of 1 August 2008.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2008.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2008, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to

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sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, evidence of intestinal inflammation), or the prior corticosteroid therapy and immunosuppressive therapy.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 9 November 2007 or infliximab prior to 7 March 2007 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Authority required

Initial treatment of Crohn disease in a paediatric patient.

Initial PBS-subsidised treatment by a gastroenterologist, paediatrician or consultant physician as specified in the NOTE below, of a patient aged 6 to 17 years inclusive with moderate to severe refractory Crohn disease who satisfies the following criteria:

- (a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and
- (b) whose parent or authorised guardian has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction

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for continuing treatment; and

(c) has failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including:

(i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period;

(ii) an 8 week course of enteral nutrition;

(iii) immunosuppressive therapy including:

— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or

— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or

— methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) severity of disease activity which results in a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30 as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) The most recent PCDAI assessment must be no more than 1 month old at the time of application.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) details of previous systemic drug therapy [dosage, date of commencement and duration of therapy], or dates of enteral nutrition; and

(iii) the signed patient acknowledgement.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Authority required

Continuing treatment of Crohn disease in a patient initiated on PBS-subsidised treatment as a paediatric patient.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, paediatrician, consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of moderate to severe refractory Crohn disease; and

(b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as a reduction in Paediatric Crohn Disease Activity Index (PCDAI) Score by at least 15 points as compared to baseline AND a total PCDAI score of 30 points or less.

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Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 - (i) the completed Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition.

The PCDAI assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, a PCDAI assessment of the patient's response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

Patients who fail to demonstrate or sustain a response to treatment with infliximab for Crohn disease as specified in the criteria for continuing treatment with infliximab, will not be eligible to receive PBS-subsidised treatment with this drug within 12 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Initial PBS-subsidised treatment of Crohn disease in a paediatric patient who has previously received non-PBS-subsidised therapy with infliximab.

Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, paediatrician, consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient aged 6 to 17 years inclusive who:

- (a) has a documented history of moderate to severe refractory Crohn disease and was receiving treatment with infliximab prior to 4 July 2007; and
- (b) had a Paediatric Crohn Disease Activity Index (PCDAI) Score of greater than 30 prior to commencing treatment with infliximab. Where a baseline CDAI assessment is not available, please call Medicare Australia on 1800 700 270 to discuss; and
- (c) whose parent or authorised guardian has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
- (d) has demonstrated or sustained an adequate response to treatment with infliximab. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as a reduction in Paediatric Crohn Disease Activity Index (PCDAI) Score by at least 15 points as compared to baseline AND a total PCDAI score of 30 points or less.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 - (i) the completed current and baseline Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition; and
 - (ii) the signed patient acknowledgement.

The current PCDAI assessment must be no more than 1 month old at the time of application. The baseline PCDAI assessment must be from immediately prior to commencing treatment with infliximab.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

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	failed to sustain a response, to treatment with infliximab.					
	Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.					
	Patients who fail to demonstrate or sustain a response to treatment with infliximab for Crohn disease as specified in the criteria for continuing treatment with infliximab, will not be eligible to recommence PBS-subsidised treatment with this drug within 12 months of the date on which treatment was ceased.					
	At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.					
	Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).					
	Patients may qualify for PBS-subsidised treatment under this restriction once only.					
5755X	Powder for I.V. infusion 100 mg (Public)	1	751.70	Remicade JC
9612X	Powder for I.V. infusion 100 mg (Private)	1	788.19	Remicade JC

INFLIXIMAB

Note

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for patients with complex refractory fistulising Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 April 2011 is considered to be in their first cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

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A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

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(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF- α antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for complex refractory fistulising Crohn disease prior to 4 November 2010 or infliximab prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Authority required

Initial 1

Initial treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:

- (a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and
- (b) has an externally draining enterocutaneous or rectovaginal fistula; and
- (c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

Authority applications must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 - (i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and
 - (ii) a signed patient acknowledgement.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6 will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Authority required

Initial 2

Change or re-commencement of treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with infliximab of complex refractory fistulising Crohn disease by a gastroenterologist or a consultant physician as

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specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:

- (a) has a documented history of complex refractory fistulising Crohn disease; and
- (b) in this treatment cycle, has received prior PBS-subsidised treatment with adalimumab or infliximab for a draining enterocutaneous or rectovaginal fistula; and
- (c) has not failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 - (i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and
 - (ii) details of prior TNF-alfa antagonist treatment including details of date and duration of treatment.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Authority required

Initial 3 (grandfather)

Initial PBS-subsidised treatment of complex refractory FISTULISING CROHN DISEASE in a patient who has previously received non-PBS-subsidised therapy with infliximab.

Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who satisfies the following criteria:

- (a) has a documented history of complex refractory fistulising Crohn disease and was receiving treatment with infliximab prior to 1 March 2010; and
- (b) had a draining enterocutaneous or rectovaginal fistula(e) prior to commencing treatment with infliximab; and
- (c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
- (d) is receiving treatment with infliximab at the time of application; and
- (e) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as:

- (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or
- (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:

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- (a) a completed authority prescription form; and
 (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 (i) a completed current and baseline Fistula Assessment form including the date of assessment of the patient's condition; and
 (ii) a signed patient acknowledgement.

The current fistula assessment must be no more than 1 month old at the time of application.

The baseline fistula assessment must be from immediately prior to commencing treatment with infliximab.

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only.

Authority required

Continuing treatment of complex refractory FISTULISING CROHN DISEASE.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

- (a) has a documented history of complex refractory fistulising Crohn disease; and
 (b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response is defined as:

- (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or
 (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Authority applications must be made in writing and must include:

- (a) a completed authority prescription form; and
 (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition.

The fistula assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, an assessment of the patient's response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks

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	of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).					
9654D	Powder for I.V. infusion 100 mg (Public)	1	751.70	Remicade JC
9674E	Powder for I.V. infusion 100 mg (Private)	1	788.19	Remicade JC

INFLIXIMAB

Note

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, infliximab and ustekinumab.

From 1 March 2010, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial adalimumab, etanercept, infliximab or ustekinumab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

A patient who received PBS-subsidised biological agent treatment for chronic plaque psoriasis prior to 1 March 2010 is considered to be in their first Cycle as of 1 March 2010.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient who, prior to 1 March 2010, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2010.

Patients must be assessed for response to each course of continuing treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis after 1 March 2010.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face,

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hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

- (i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or
- (ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or
- (iii) patients who wish to re-commence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab and etanercept, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to Medicare Australia within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course of a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with adalimumab, etanercept, infliximab or ustekinumab it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

Patients who commenced treatment with adalimumab prior to 1 June 2009 or ustekinumab prior to 1 March 2010 access these interchangeability arrangements in the same way as patients who have not.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

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Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

Authority required

Initial treatment [Initial 1, Whole body (New patients — No prior biological agent)]

Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

- (a) have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; and
- (b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
- (c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body); and
- (d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:
 - (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or
 - (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or
 - (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or
 - (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

- (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
- (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
- (c) The most recent PASI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 - (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
 - (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
 - (iii) the signed patient and prescriber acknowledgements.

A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.

A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Authority required

Initial or re-Treatment [Initial 2, Whole body (Received prior biological agent under PBS)]

Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

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- (a) have a documented history of severe chronic plaque psoriasis; and
- (b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
- (c) have not failed PBS-subsidised therapy with infliximab for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 - (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
 - (ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised infliximab treatment within this Treatment Cycle and who wish to re-commence infliximab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised infliximab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.

A PASI assessment of the patient's response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Authority required

Continuing treatment (Whole body)

Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:

- (a) who have a documented history of severe chronic plaque psoriasis; and
- (b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with infliximab; and
- (c) who have demonstrated an adequate response to their most recent course of treatment with infliximab.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-biological treatment baseline value for this Treatment Cycle.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 - (i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet along with the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with infliximab.

A maximum of 24 weeks of treatment with infliximab will be authorised under this restriction.

HIGHLY SPECIALISED DRUGS PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
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At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Authority required

Initial treatment [Initial 1, Face, hand, foot (New patients — No prior biological agent)]

Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

- (a) have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and
- (b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
- (c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot); and
- (d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:
 - (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or
 - (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or
 - (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or
 - (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

- (a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:
 - (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or
 - (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
- (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
- (c) The most recent PASI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 - (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
 - (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
 - (iii) the signed patient and prescriber acknowledgements.

A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

HIGHLY SPECIALISED DRUGS PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
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Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.

A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Authority required

Initial or re-Treatment [Initial 2, Face, hand, foot (Received prior biological agent under PBS)]

Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

- (a) have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and
- (b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
- (c) have not failed PBS-subsidised therapy with infliximab for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 - (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
 - (ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised infliximab treatment within this Treatment Cycle and who wish to re-commence infliximab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised infliximab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.

A PASI assessment of the patient's response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Authority required

Continuing treatment (Face, hand, foot)

Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:

- (a) who have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and

HIGHLY SPECIALISED DRUGS PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
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- (b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with infliximab; and
(c) who have demonstrated an adequate response to treatment with infliximab.

An adequate response to infliximab treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams along with the date of the assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

The most recent PASI assessment must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note

No applications for increased repeats will be authorised.

5758C	Powder for I.V. infusion 100 mg (Public)	1	751.70	Remicade	JC
9617E	Powder for I.V. infusion 100 mg (Private)	1	788.19	Remicade	JC

MARAVIROC

Authority required (STREAMLINED)

3599

Treatment, in addition to optimised background therapy in combination with other antiretroviral agents, of an antiretroviral experienced patient infected with only CCR5-tropic HIV-1, who, after each of at least three different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes, has experienced virological failure or clinical failure or genotypic resistance. A tropism assay to determine CCR5 only strain status is required prior to initiation. Individuals with CXCR4 tropism demonstrated at any time point are not eligible.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

5792W	Tablet 150 mg (Public)	120	5	..	*1835.40	Celsentri	VI
5793X	Tablet 300 mg (Public)	120	5	..	*1835.40	Celsentri	VI

HIGHLY SPECIALISED DRUGS PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
MARAVIROC						
<u>Authority required</u>						
Treatment, in addition to optimised background therapy in combination with other antiretroviral agents, of an antiretroviral experienced patient infected with only CCR5-tropic HIV-1, who, after each of at least three different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes, has experienced virological failure or clinical failure or genotypic resistance. A tropism assay to determine CCR5 only strain status is required prior to initiation. Individuals with CXCR4 tropism demonstrated at any time point are not eligible.						
Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.						
9572T	Tablet 150 mg (Private)	120	5	..	*1881.82	Celsentri VI
9573W	Tablet 300 mg (Private)	120	5	..	*1881.82	Celsentri VI
METHYLPREDNISOLONE						
<u>Note</u>						
Pharmaceutical benefits that have the form methylprednisolone powder for injection 40 mg (as sodium succinate) and pharmaceutical benefits that have the form methylprednisolone powder for injection 40 mg (as sodium succinate) with diluent are equivalent for the purposes of substitution.						
2981X NP	Powder for injection 40 mg (as sodium succinate) with diluent	5	30.47 31.56 ^a	Solu-Medrol PF
METHYLPREDNISOLONE						
<u>Note</u>						
Pharmaceutical benefits that have the form methylprednisolone powder for injection 1 g (as sodium succinate) and pharmaceutical benefits that have the form methylprednisolone powder for injection 1 g (as sodium succinate) with diluent are equivalent for the purposes of substitution.						
8834Y NP	Powder for injection 1 g (as sodium succinate) with diluent	1	79.69 34.20 ^a	Solu-Medrol PF
SIROLIMUS						
<u>Caution</u>						
Careful monitoring of patients is mandatory.						
<u>Authority required (STREAMLINED)</u>						
3355						
Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of renal allograft rejection. Management includes initiation, stabilisation and review of therapy as required.						
9549N	Tablet 1 mg (Public)	200	5	..	*1446.66	Rapamune PF
9548M	Tablet 2 mg (Public)	200	5	..	*2893.34	Rapamune PF
9550P	Oral solution 1 mg per mL, 60 mL (Public)	2	5	..	*936.00	Rapamune PF
SIROLIMUS						
<u>Caution</u>						
Careful monitoring of patients is mandatory.						
<u>Authority required</u>						
Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of renal allograft rejection. Management includes initiation, stabilisation and review of therapy as required.						
6436R	Tablet 1 mg (Private)	200	5	..	*1493.08	Rapamune PF
6457W	Tablet 2 mg (Private)	200	5	..	*2939.76	Rapamune PF
6437T	Oral solution 1 mg per mL, 60 mL (Private)	2	5	..	*979.86	Rapamune PF

SECTION 100 (HUMAN GROWTH HORMONE)

Code	Name, Restriction, Manner of Administration and Form	Pack Size	Price ex manufacturer \$	Brand Name and Manufacturer
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SOMATROPIN (Recombinant human growth hormone)

Criteria for availability

Short stature in accordance with the 'Guidelines for the Availability of Human Growth Hormone (hGH) as a Pharmaceutical Benefit'.

Genotropin branded products (including MiniQuick) are also available for the treatment of Prader-Willi Syndrome in accordance with the 'Guidelines for the Availability of Human Growth Hormone (hGH) as a Pharmaceutical Benefit for the treatment of Prader-Willi Syndrome'.

Note

These guidelines may be obtained from the Department of Health and Ageing's internet site at <http://www.health.gov.au/hGH>, or from:

Growth Hormone Program
Access and Systems Branch
Department of Health and Ageing
GPO Box 9848
CANBERRA ACT 2601
Contact telephone number (02) 6289 7274

6310D	Injection 10 mg (30 i.u.) vial with diluent (with preservative)	1	495.00	Zomacton	FP
6266T	Injection 4 mg (12 i.u.) vial with diluent (with preservative)	1	198.00	Zomacton	FP

REPATRIATION PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
BANDAGE—CALICO							
4717G	Bandage, triangular, large	#1	13.49	5.60	Handy 36361414 BV
BANDAGE—COMPRESSION							
Note							
Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.							
4736G	Bandage, high stretch, 7.5 cm x 3 m	5	*94.32	5.60	Tensopress 71723-01 BV
4748X	Bandage, high stretch, 10 cm x 3 m	5	*72.92	5.60	Surepress 650947 CC
					*126.62	5.60	Tensopress 71723-00 BV
4654Y	Bandage, short stretch, 8 cm x 2.6 m	5	*77.77	5.60	Comprilan 01027-00 BV
DRESSING—FILM ISLAND							
Note							
Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.							
4898T	Dressings 5 cm x 7.2 cm, 5	2	*28.92	5.60	Cutifilm Plus 36361370 SN
4899W	Dressings 8 cm x 10 cm, 5	2	*45.50	5.60	Cutifilm Plus 36361371 SN
DRESSING—GAUZE (ABSORBENT PAD)							
4707R	Pads 5 cm x 5 cm, 100	#1	13.88	5.60	Handy 71117-05 BV
4708T	Pads 10 cm x 10 cm, 100	#1	27.40	5.60	Handy 71117-06 BV
DRESSING—NON-ADHERENT							
Note							
Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.							
4819P	Dressings 5 cm x 5 cm, 5	2	*15.80	5.60	Cutilin Non-Stick Wound Pad 36361374 SN
4862X	Dressings 10 cm x 10 cm, 5	2	*25.40	5.60	Cutilin Non-Stick Wound Pad 36361375 SN
TAPES—PLASTER ADHESIVE ELASTIC							
4780N	Roll 2.5 cm x 2.5 m	#1	12.76	5.60	Leukoplast 01071-00 BV
4781P	Roll 5 cm x 2.5 m	#1	18.56	5.60	Leukoplast 01072-00 BV
4782Q	Roll 7.5 cm x 2.5 m	#1	22.13	5.60	Leukoplast 01073-00 BV